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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,875	02/08/2000	Richard Griffey	IBIS-0261	1850

7590

08/07/2002

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EXAMINER

FRIEND, TOMAS H F

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 08/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Applicant N .

09/499,875

Applicant(s)

GRIFFEY ET AL.

Examiner

Tomas Friend

Art Unit

1627

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 July 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_


3. ☒ Applicant's reply has overcome the following rejection(s): objection to claim 37.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 30-46.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
JOSEPH K. MCKANE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Tomas Friend, Ph.D.  
30 July 2002

Continuation of 5. does NOT place the application in condition for allowance because: [1] With respect to the rejections under 35 U.S.C. 112, second paragraph, applicants argue that the case law cited by applicants indicates that "just because a claim includes a term of degree does not automatically render the claim indefinite." Applicants' argument has been carefully considered and found not to be persuasive. Although there are cases in which relative terminology is used without making a claim indefinite, the examiner maintains that in this particular instance, the terms "diverse compounds" and "related compounds" do not provide one of ordinary skill in the art a means of determining whether a particular set of compounds one wishes to use would infringe on the presently claimed invention. Without a means of determining the degree or form of relatedness between compounds or the degree or form of diversity among compounds encompassed by the rejected claims, a potential infringer could reasonably argue that a set of compounds may be considered by one person of ordinary skill in the art to be related while another would consider the same set to be diverse. For example, the 20 amino acids used in protein synthesis can be considered to be related because they are all alpha-amino acids. They may also be considered to be diverse because their side chains vary tremendously in structure, hydrophobicity, nucleophilicity, size, and charge, for example. Applicants request that the examiner identify which limitations applicants are reading into the claims, based upon applicants' arguments regarding diverse and related compounds. Applicants argue that "any degree of diversity or relatedness is suitable for the invention, and one skilled in the art would understand this in light of the specification." To any extent that the specification may provide the means to "understand" the metes and bounds of diverse and related compounds, those means are "read into" the claims.

[2] With respect to the rejection of claims 30-46 under 35 U.S.C. 112, first paragraph, applicants argue that the rejection is improper because "it is directed to the examiner's interpretation of the claimed invention rather than to what the claim actually recites." Applicants argue that the method steps recited in claim 30, for example, are enabled and that the examiner has not provided any credible evidence that any of the method steps would require undue experimentation. Applicants' arguments have been carefully considered and found not to be persuasive. The reasoning provided for the original rejection of record (i.e. Wands analysis) is reproduced below for applicants' convenience.

"In the present case, the claims encompass any target molecule, any "standard compound" and any group of (test) compounds whatsoever. The state of the prior art was such that known ligands known to bind to specific sites on a target molecule could be used as "standard compounds" and that their displacement from a target molecule by a test compound with higher affinity for that specific site on the molecule could be detected and quantified by mass spectrometry. The predictability of detecting the binding of a test compound to a target molecule by the displacement of a "standard compound" with no limitation that the test and "standard" compounds bind the same sites on the target molecule is very low, particularly with larger target molecules and smaller test molecules. The inventor provides no working example to exemplify the use of the claimed method. The specification provides only general guidance with respect to selection of "standard" compounds (e.g. the use of ammonium ion or amine-containing standard ligands) and provides insufficient guidance with respect selecting different types of "standard" compounds for use with different types of target molecules or how to select "standard" compounds that are detectable by mass spectrometry and able to bind a target molecule. The specification appears to direct one of ordinary skill in the art to use non-specific "standard" compounds which may or may not bind the target molecule of interest and may or may not bind at a site on the target that is of interest to one using the invention. Substantial experimentation would be required to determine what "standard" compounds (in what amounts) can be used (selected) with a particular target molecule that simultaneously satisfy the requirements for detection by mass spectrometry, binding affinity, and binding to the site of interest on the target molecule, for example."

Applicants list individual method steps and argue that each of the individual method steps can be performed without undue experimentation. Applicants request that the examiner explicitly point out what undue experimentation is allegedly required to carry out any particular step in the recited claims. The rejection under 35 U.S.C. 112, first paragraph, is not made against each method step individually. The rejection states that the subject matter was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. The factors to be considered include the breadth of the claims, the state of the prior art, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. The original rejection includes a "Wands analysis" and the examiner has answered all arguments made with regard to that analysis. Applicants' arguments have been found not to be persuasive and the rejection is maintained.